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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,100	06/20/2003	Vesna Kostanjevecki	INNS:038 11362.0038.NPUS0	7038

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EXAMINER	
LYLES, JOHNALYN D	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,100	KOSTANJEVECKI ET AL.	
	Examiner	Art Unit	
	Johnalyn Lyles	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, drawn to a method *for screening, differential diagnosis and/or prognosis in a mammal, for identifying a mammal at risk, or for monitoring the effects of therapy administered to a mammal with Alzheimer's disease (AD), frontotemporal dementia (FTD), dementia with Lewy bodies (DLB), vascular dementia (VAD) and/or depression*, by **detecting** the level of at least one neurological disease-associated protein, **comparing** the level of the protein detected with 1) a range of levels, 2) with the level of the protein in a control mammal 3) with the level of the protein in another neurological disease, 4) with a previously defined cut-off value suitable for differentiating between AD and a) depression, b.) FTD or c) VAD and **concluding** from the comparison whether the mammal is suffering from AD, FTD, DLB, VAD, depression, whereby a level of said protein or isoform in a range previously defined as characteristic, or an altered level compared to said level in a control animal, or above/below the cut-off value is an indication said mammal is suffering from AD, FTD, DLB, VAD, or depression, classified in class 436, subclasses 86, 500, 512, or 515.

II. Claim 19, drawn to a composition comprising an isolated protein associated with AD, FTD, DLB, VAD, and/or depression classified in class 514, subclass 2.

III. Claim 20-25, drawn to an antibody capable of specifically recognizing one of the proteins associated with AD, FTD, DLB, VAD, and/or depression, classified in class 530, subclass 387.1.

IV. Claim 26, drawn to a method of screening for agents that interact with and/or modulate the expression or activity of a protein, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together and have different functions. Group I is a method for screening, differential diagnosis and/or prognosis in a mammal, for identifying a mammal at risk, or for monitoring the effects of therapy administered to a mammal with Alzheimer's disease (AD), frontotemporal dementia (FTD), dementia with Lewy bodies (DLB), vascular dementia (VAD) and/or depression. Group II is a composition comprising an isolated protein associated with AD, FTD, DLB, VAD, and/or depression that may be used for treatment of a particular disease.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, detection of the protein can be practiced with another materially different product, for example a ligand or silver staining or Coomassie blue staining methods and reagents.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are different methods not disclosed as capable of use together and that have different functions. Group I is a method for screening, differential diagnosis and/or prognosis in a mammal, for identifying a mammal at risk, or for monitoring the effects of therapy administered to a mammal with Alzheimer's disease (AD), frontotemporal dementia (FTD), dementia with Lewy bodies (DLB), vascular dementia (VAD) and/or depression, whereas Group IV is a method of screening for agents that interact with and/or modulate the expression or activity of a protein.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are different products not disclosed as capable

of use together and that have different functions. Group II is a composition comprising an isolated protein associated with AD, FTD, DLB, VAD, and/or depression that may be used for treatment of a particular disease. Group III is an antibody capable of specifically recognizing one of the proteins associated with AD, FTD, DLB, VAD, and/or depression.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together and that have different functions. Group II is a composition comprising an isolated protein associated with AD, FTD, DLB, VAD, and/or depression that may be used for treatment of a particular disease, and Group IV is a method of screening for agents that interact with and/or modulate the expression or activity of a protein.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together and that have different functions. Group III is an antibody capable of specifically recognizing one of the proteins associated with AD, FTD, DLB, VAD, and/or depression. Group IV is a method of screening for agents that interact with and/or modulate the expression or activity of a protein.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and/or their different classification, restriction for examination purposes as indicated is proper.

Further Restriction Groups

Further election is **required** with the restriction as set forth in the following Groups (A-C).

If applicant elects any of the inventions I-IV, Applicant must further elect one (1) neurological disease-associated protein, (1) neurological disease, and one (1) comparison for a single invention as set forth below. If Applicant elects Invention I-IV, then select one neurological disease indicated by the method from Group A, one neurological disease-associated protein detected from Group B, and one comparison:

Group A:

1. Alzheimer's disease (AD),
2. Frontotemporal dementia (FTD),
3. Dementia with Lewy bodies (DLB),
4. Vascular dementia (VAD)
5. Depression

Group B:

Apo E, α-1-antitrypsin, α-1-β glycoprotein, antithrombin III, Apo A-I, Apo A-IV, Apo J, gelsolin, haptoglobin, hemopexin, Ig α-1 chain C region (heavy),

kininogen, prostaglandin-H2 D-isomerase, transthyretin, vitamin D-binding protein, Zn-α-2-glycoprotein

Group C:

1) **comparing** the level of at least one protein detected with a range of levels previously defined as characteristic for mammals suffering from AD, FTD, DLB, VAD, or depression and control mammals or

2) **comparing** the level of at least one protein detected with the level of at least one protein in a control mammal, or

3) **comparing** the level of at least one protein detected with the level of at least one protein in a mammal suffering from another neurological disease,

4) **comparing** the level of at least one protein detected with a previously defined cut-off value suitable for differentiating mammals suffering from AD versus mammals suffering from FTD

5) **comparing** the level of at least one protein detected with a previously defined cut-off value suitable for differentiating mammals suffering from AD versus mammals suffering from depression

6) **comparing** the level of at least one protein detected with a previously defined cut-off value suitable for differentiating mammals suffering from AD versus mammals suffering VAD

The inventions are distinct, each from the other because of the following reasons: the inventions are drawn to **different methods, compositions, and antibodies** associated with different neurological disorders, affecting different populations, and

having different characteristics; different proteins with different sequences, structures and functions and expression/association with said disorders; and different comparisons among different proteins and populations with different effects and indications.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their divergent subject matter, restriction for examination purposes as indicated is proper.

For Applicant to be fully responsive to the restriction requirement, **(1) neurological disease, (1) neurological disease-associated protein, and one (1) comparison from Groups A-C** must be elected for the elected invention. Applicant is advised that a reply to this requirement must include identification of the invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. The Examiner notes that this is not a species election requirement; rather it sets forth additional invention groups.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention: neurological disease-associated protein isoforms.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Johnalyn Lyles** whose telephone number is **571-272-3433**. The examiner can normally be reached on **M-F 8 am - 4 pm**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jdl

SHARON TURNER, PH.D.
PRIMARY EXAMINER

6-8-05